Complete Summary

GUIDELINE TITLE

Acne management.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Acne management. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Sep. 32 p. [54 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: Institute for Clinical Systems Improvement (ICSI). Acne Management. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2002 Nov. 31 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acne

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve the selection of appropriate treatment for patients with acne based on severity
- To increase the number of patients who report satisfaction with the treatment of their acne
- To increase the number of patients with appropriate follow up for acne treatment

TARGET POPULATION

All patients with acne vulgaris

Note: This guideline excludes rosacea and folliculitis.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Review of possible contributing factors including hormonal, mechanical, and medications
2. Assess objective severity of acne (e.g., mild, moderate, or severe)
3. Assess psychosocial impact of acne

Treatment/Management

1. Develop goals of treatment including clearance of acne; prevention of scarring; and learning to cope with psychological stress from acne
2. Over-the-counter topical products that may contain benzoyl peroxide, salicylic acid, or glycolic acid, sulfur, or resorcinol (Benzac®, Desquam-X®, PanOxyl®, generics)
3. Topical retinoids such as adapalene (Differin®), tazarotene (Tazorac®), tretinoin (Retin-A®, generics, Avita®, Retin-A Micro®)
4. Azelaic acid (Azelex®)

5. Topical single drug antibiotic products such as clindamycin (Cleocin T®, generics), erythromycin (A/T/S®, Erygel®, Eryderm®, generics), sulfacetamide (Klaron®)
6. Topical combination drug antibiotic products such as benzoyl peroxide + clindamycin (BenzaClin®), benzoyl peroxide + erythromycin (Benzamycin®), sulfacetamide + sulfur (Clenia®, Avar®, Plexion®, Rosanil®, Novacet R®, Sulfacet-R®, generic)
7. Topical treatments plus oral antibiotics such as erythromycin (Erytabs®, generics), doxycycline, minocycline (Minocin®, generics), tetracycline, clindamycin (Cleocin®, generics), sulfamethoxazole/trimethoprim (Bactrim®, Septra®, generics)
8. Patient education, follow-up, and encouragement
9. Adjunctive therapy such as oral contraceptives, spironolactone, oral retinoids, intra-lesional injections, Blue Light (ClearLight - Lumenis)
10. Referral to dermatologist

MAJOR OUTCOMES CONSIDERED

- Patient factors such as contributing medical conditions and medications
- Severity of acne (presence and quantity of papules, pustules, nodules, cysts, and total lesions)
- Quality of life and other psychosocial factors
- Results/outcome of treatments
- Side effects of treatment
- Patient compliance and adherence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented

below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Committee on Evidence-Based Practice carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for acne management are presented in the form of an algorithm with 10 components, accompanied by detailed annotations. An algorithm is provided for Acne Management; clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Patient perception of improvement is the best measure of successful treatment. (Annotation #4)
2. Although acne is not a life threatening disease, the clinician must be aware of potentially debilitating psychosocial effects. (Annotation #4)
3. Treatment with both a topical retinoid and a topical antibiotic has been found to be an effective course of treatment. (Annotation #5)
4. Customize a treatment plan that the patient will be able to follow according to his/her needs. (Annotations #6, 8)
5. The patient needs to understand that acne may get worse before it gets better. It typically takes eight weeks of treatment before a response is noted. (Annotation #7)
6. Accutane therapy should be considered only after several attempts of other treatment regimens. (Annotation #9)

Algorithm Annotations

1. Patient Presents for Treatment of Acne

   This guideline refers to acne vulgaris. This guideline excludes:

   - Rosacea
   - Folliculitis
2. Review Possible Contributing Factors

   Hormonal

Signs of androgen excess would include:

- Precocious puberty
- Hirsutism

Possible causes of androgen excess would include:

- Polycystic ovary disease
- Adrenal tumor
- Ovarian tumor
- Pituitary tumor

Mechanical

On rare occasions physical occlusion may contribute to acne. For example: hockey masks; oil-based cosmetics (although most cosmetics today are water based).

Evidence supporting this recommendation is of classes: D, R

Medications

There are many medications that may contribute to the development of acne. In addition to treating the acne, consideration may be given to discontinuing these medications. Refer to the original guideline document for a list of medications that may contribute to the development of acne.

3. Assess Objective Severity of Acne

Acne severity is the most important clinical diagnostic tool in studies reviewed. For simplification, the guideline developer is following the Agency for Healthcare Research and Quality's (AHRQ) recommendation to divide acne into three severity grades: mild, moderate, and severe. There are a number of other ways of grading acne that are used clinically and in research. None, however, is universally accepted. Additionally, psychological impact or the presence of scarring may play a role in assigning a severity grade to the patient.

The following diagnostic tool was designed as a guideline for three lesion counts on the face but may be applicable to grading the severity of acne on the trunk as well.

a. Mild Acne:

Mild acne is characterized by predominance of comedones (fewer than 20), or fewer than 15 inflammatory papules, or a comedone/papule count of fewer than 30 on the face.

b. Moderate Acne:

Moderate acne predominantly exhibits papules and pustules (about 15-50 lesions) with comedones and rare cysts. Total lesion (comedone, papule, pustule) count may range from 30 to 125 on the face.

c. Severe Acne:

Severe acne is characterized primarily with the presence of inflammatory nodules and cysts. Also present are comedones, papules, and pustules or total lesion count of greater than 125 on the face.

Definitions:

- Closed Comedone (whitehead): non-inflamed (non-red) follicular opening containing a keratotic plug with a thin overlying epidermal membrane
- Open Comedone (blackhead): non-inflamed (non-red) follicular opening containing a keratotic plug that appears black
- Papule: small round to oval red elevation of the skin (1-4 mm)
- Pustule: resembles a papule with a central pocket of pus
- Nodule/Cyst: poorly marginated red tender, sometimes draining 0.2- to 3.0-cm indurated mass in the skin

Evidence supporting this recommendation is of classes: M, R

4. Assess Psychosocial Impact of Acne

It is important to assess the psychosocial effect of acne. Studies using "quality of life" surveys show a variety of significant impacts, most frequently, anxiety and depression. Decreased self-esteem, social withdrawal, anger, conduct disorders, and decreased employability have been reported in other studies. The clinical severity of the acne does not always predict the severity of the psychosocial impacts. Effective treatment of acne can decrease these negative effects.

If significant psychosocial effects are present, consider a more aggressive initial treatment than might be indicated by the objectively observed severity alone. Patient perception of improvement is the best measure of successful treatment.

Evidence supporting this recommendation is of classes: C, D, R

5. Choose Treatment Plan

There are multiple treatment modalities that have been demonstrated effective in the treatment of acne. [Conclusion Grade I: See Discussion Appendix A, Conclusion Grading Worksheet - Annotation #5 (Choose Treatment Plan) in original guideline document.]

When initiating treatment it is important to consider the goals of therapy. Treatment goals should include:

- Achieving clearance of acne
- Prevention of scarring
- Learning to cope with psychological stress resulting from the acne

Considerations:

- Patient skin type (oily to dry)
    - for very oily skin consider a gel or solution
    - for very dry skin choose creams or lotions
- If more than one topical is being used (for example a retinoid and a topical antibiotic), have patient apply one in the morning and the other at night.
- If multiple agents are used, they should be from different classes. For example, a benzoyl peroxide and a topical antibiotic.
- Customize treatment to enhance adherence. For example, can the patient reach their back to apply the product? Importance of avoiding food, especially dairy products, one hour before or two hours after taking tetracycline.

a. Topical Treatment of Acne

An example of treatment for mild acne may include benzoyl peroxide, a topical antibiotic, or a combination product one to two times daily; or a topical retinoid once daily in addition to the above. See tables in this annotation in the original guideline document for description of medications.

Over-the-counter Topical Products

A wide variety of over-the-counter (OTC) topical products are available to the patient for self-treatment of acne. A complete listing is beyond the scope of this publication. The most common ingredient in OTC products is benzoyl peroxide in concentrations up to 10%. Salicylic acid in concentrations of 0.5% to 2% is a keratolytic found in many OTC acne products. Products may also contain glycolic acid (an alpha-hydroxy acid), sulfur, or resorcinol. When evaluating a new patient it is helpful to know which products they may have tried.

Benzoyl Peroxide

Benzoyl peroxide is available without a prescription in products such as Clearasil® and by prescription in the products listed in the original guideline document. It is also available in combination with antibiotics (see Topical Antibiotics table in the original guideline document).

Topical Retinoids for Acne

Topical retinoids (see Topical Retinoids table in the original guideline document) increase the turnover of follicular epithelial cells, promote drainage of comedones, and inhibit new comedone (blackhead,

whitehead) formation. Topical retinoids are generally applied in the evening.

Azelaic Acid

Azelaic acid is a naturally occurring dicarboxylic acid which has been shown to be effective in reducing both inflammatory and non-inflammatory acne lesions (see Azelaic Acid table in the original guideline document.)

Topical Antibiotics for Acne

Propionibacterium acnes (P. acnes) is an anaerobic bacterium present within the pilosebaceous follicles. It is thought that this microorganism plays a role in acne-associated inflammation. The antibiotics used to treat acne have been shown to reduce colonization of P. acnes and may also possess direct anti-inflammatory effects. In-vitro resistance of P. acnes to commonly used antibiotics has been increasing but the clinical significance of this is uncertain. However, it has been recommended that antibiotics be used with either topical retinoids or benzoyl peroxide. (See Single Drug Products and Combination Products tables in the original guideline document.)

b. Topical Treatment and Oral Antibiotics for Acne

An example for moderate/severe acne may include examples listed in section 5a of the original guideline document with the addition of an oral antibiotic while continuing with the topical treatment. (See First Line Antibiotics and Second Line Antibiotics tables in the original guideline document for descriptions of products.)

Evidence supporting this recommendation is of classes: A, C, D, R

6. Patient Education

Successful management of acne is dependent on a successful partnership between the health care team and the patient. Non-adherence is one of the biggest causes of treatment failure. Clear guidelines regarding treatment, possible adverse effects and realistic expectations of treatment outcomes should be given to the patient to achieve the best possible outcomes. Ongoing patient education, follow-up, encouragement, and maintaining a positive approach are vital. Because acne can be so devastating for many, early intervention with a proactive treatment plan may well prevent some of the long-term physical and psychosocial consequences.

Myths and Facts

An integral component of the prevention and treatment of acne is discussion of the facts and expulsion of the myths.

MYTH: Any acne medication works immediately.

FACT: It can take at least eight weeks of a prescribed treatment regimen for the patient to see any improvement. Acne may even get worse before it gets better.

MYTH: Acne is a result of poor hygiene.

FACT: As a result of this myth, people tend to overwash their skin, often scrubbing hard with abrasive cleansers. Cleaning the skin too often may aggravate acne and cause flare ups. Wash face twice per day with a mild soap; pat dry and use appropriate acne treatment. Acne is not caused by dirt or surface oil.

MYTH: Washing many times a day will diminish acne.

FACT: Under normal circumstances, wash no more than two times a day with mild soap and lukewarm, not very hot or very cold water.

MYTH: Washing with abrasive soaps, cleansing granules, astringents, vigorous scrubbing, or a buff puff will clear up acne on the face.

FACT: Using your fingertips or a soft wash cloth is best.

MYTH: Picking your acne will make it go away.

FACT: This may cause scarring. Do not pick at acne lesions.

MYTH: Once acne has cleared up, it will be gone forever.

FACT: There is no cure for acne. If acne medication is discontinued, acne will probably flare.

MYTH: Stress causes acne.

FACT: Stress alone does not cause acne but may exacerbate psychological reaction to the acne. Acne is caused by overactive oil glands stimulated by androgens mixing with dead skin cells. This is particularly true during the teenage years when androgen production is at its highest.

MYTH: Eating chocolate and sugar will cause acne.

FACT: There is no evidence to support this. Certain foods may make some patients' acne worse and obviously should be avoided. No specific food has been proven to worsen acne. No diet has been shown to be beneficial.

MYTH: Teenagers are the only ones affected by acne.

FACT: Acne affects adults as well as children. The body produces androgens throughout life. The circumstances around adult acne may be a little different than in teens, particularly in women. Women between 18 and 40 years may have breakouts that occur most frequently when they are premenstrual.

Home care recommendations

- Topical medications should be applied to dry skin.
- Try to avoid abrasive soaps, cleansing granules, astringents, and vigorous scrubbing.
- Under normal circumstances, wash no more than two times a day with your fingertips or a soft wash cloth.
- Patients who are treated with acne medications often develop dry skin. Use fragrance-free, non-comedogenic, oil-free moisturizers. These moisturizers will not clog pores and therefore should not cause black- or whiteheads.
- For patients who choose to use makeup to cover their acne lesions, a water-based, non-comedogenic makeup should be used. Avoid oil-based cosmetics. Use makeup sparingly.
- Do not cover acne with bandages or tight fitting clothing.
- If a topical retinoid or photosensitizing antibiotics are prescribed, recommend staying out of the sun as much as possible and stress the use of sunscreens.

Evidence supporting this recommendation is of class: R

7. Follow-Up 8-12 Weeks/Satisfactory Response?

   There is no clear evidence to support a specific duration of any treatment for acne. However, clinical experience and clinical trials suggest that a minimum treatment period of 8 to 12 weeks is needed before an improvement will be noted in most patients.

8. Assess Outcome and Adherence

   Asking non-threatening, open-ended questions during patient interviews can be a useful method of assessing medication adherence. The interview should include probes for factors that contribute to non-adherence including adverse reactions, misunderstandings of asymptomatic or chronic disease treatment, depression, cognitive impairment, complex dosing regimens, and financial constraints.

   A. Assess the patient's knowledge of his/her medication and medical condition.
   B. Assess the patient's medication administration process.
   C. Assess the patient's barriers to adherence.

   To view sample assessment questions, refer to the original guideline document.

   Evidence supporting this recommendation is of class: R

9. Modify Treatment Plan

   Consider different/additional medications

It may be necessary to switch to a different class of topical acne medication. For example: if the patient is on a benzoyl peroxide product or a combination product and is not responding, consider switching to a once daily topical retinoid and a once daily topical anti-infective. For moderate to severe acne, consider adding an oral antibiotic or switching the current oral antibiotic.

Consider adjunctive therapy

- Oral contraceptives

  The addition of combination oral contraceptives has been shown to be effective in the treatment of acne. [Conclusion Grade I: See Discussion Appendix B, Conclusion Grading Worksheet - Annotation #9 (Oral Contraceptives) in the original guideline document.]

  Treatment with a combined oral contraceptive (estrogen and progestin) is an alternative for women who fail conventional acne therapies. Oral contraceptives are effective for the treatment of acne due to their androgen modulating properties. It is the estrogen component of combined oral contraceptives that reduces androgen production and decreases the amount of free and active testosterone by increasing the production of sex hormone binding globulin. Progestin-only oral contraceptives are not effective and may worsen acne. Responses may not be seen for 3 to 6 months, with some patients showing a flare of symptoms during early cycles. Although some progestins have exhibited androgenic properties during in vitro and animal studies, all combination oral contraceptives have antiandrogenic properties due to the estrogen component. To ensure adherence with therapy, the ideal product is one that has the lowest incidence of adverse effects for a particular patient. Products with Food and Drug Administration (FDA) indications for acne include Estrostep® and Ortho Tri-cyclen®.

- Spironolactone

  Spironolactone is a medication primarily used in the treatment of hypertension. Due to its antiandrogenic effect, it has occasionally been used to treat adult-onset acne in women when other treatments have been ineffective. It is the effects of testosterone that are felt to be a contributing factor to the development of acne in adult females. The drug acts by blocking the effects of testosterone on the oil glands and hair follicles of the female patient. The result is a reduction in oil production that may lead to improvement of their acne. The optimal dosage varies, but ranges from 50 to 200 mg daily. Response may take two to three months. The drug should not be used in pregnancy. Women of child-bearing age should use birth control methods while taking the medication. Side effects are rare, usually related to menstrual irregularity, mild gastrointestinal (GI) upset, or headache. The medication may be taken for one to two years with periodic rest periods.

- Oral Retinoids

Accutane therapy should be considered only in patients who have severe recalcitrant acne or who have failed treatment with other acne medications including oral antibiotics. Isotretinoin (Accutane®), an oral retinoid, is highly effective in treating acne and is indicated for treatment of severe cystic recalcitrant nodular acne. It reduces sebum secretion and is given in doses of 0.5 to 2 mg/kg/day given with food and divided into 2 doses for 15 to 20 weeks. This may result in prolonged remissions in many patients. If acne does reoccur, retreatment with isotretinoin after 2 months is an option. However, isotretinoin can cause severe birth defects if taken during pregnancy. Other side effects include possible changes in liver function, increased cholesterol and triglycerides and a possible association with an onset or worsening of depression. Isotretinoin commonly causes dryness of the skin and mucosal surfaces including the eyes and lips (cheilitis). Arthralgias and headache have also been noted. Isotretinoin is photosensitizing.

In response to these side effects, especially the birth defects, the Food and Drug Administration restricted Accutane® prescriptions in April 2002. Highlights of the restriction include:

- Physicians who wish to prescribe Accutane® must be enrolled in a new "S.M.A.R.T" program (System to Manage Accutane Related Teratogenicity) maintained by Roche pharmaceuticals.
- Patients must sign an informed consent.
- Female patients must have 2 negative pregnancy tests prior to initiating therapy and monthly pregnancy tests during therapy and agree to use two forms of contraception simultaneously.
- Quantities are limited to a 30-day supply; neither new prescriptions nor refills may be phoned in.

Complete Accutane® prescribing information, www.rocheusa.com/products/accutane/pi.pdf.

FDA information on Accutane®, www.fda.gov/cder/drug/infopage/accutane/default.htm.

- Intra-lesional injections

  There are rare circumstances in which you may consider injecting large acne cysts with a corticosteroid for short term cosmetic improvement. Each injection carries a risk of causing skin atrophy. Repeated injections are not recommended. The concentration of Triamcinolone varies from 2 to 10 mg/cc. The stock 10-, 25- or 40- mg/ml steroid suspension should be diluted with lidocaine and only enough injected through a 1-ml syringe with a 27- or 30- gauge needle to distend the cyst slightly (usually 0.025 ml to 0.1 ml).

Blue Light (ClearLight - Lumenis)

ClearLight is a high intensity, narrow band blue light that has been approved by the FDA for the treatment of moderate acne. Clinical studies, to date, are

limited. Outcome data are insufficient. One course of treatment with ClearLight consists of 15 minute exposure, two times per week for four weeks. Treatment follow-up is also limited. It must also be noted that the high intensity lamp is expensive and patient costs are high.

Consider dermatology referral

Dermatologists treat all forms of acne, particularly severe cases. For those patients with severe inflammatory acne that has not improved with previously described medications, a retinoid, isotretinoin (Accutane), may be considered. Dermatologists may be helpful to guide you in any point of the algorithm.

Evidence supporting this recommendation is of class: A, R

10. Maintenance

If stable on current topicals, continue treatment indefinitely.

If stable on topical and systemic antibiotics, after clearance is achieved for 1 to 3 months consider tapering oral antibiotics and continue topicals indefinitely.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusions because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or inadequacy of sample sizes. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence that directly supports or refutes the conclusion.

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A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Acne Management.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits of Recommendations

Effective treatment of acne can decrease such negative effects of acne as decreased self-esteem, social withdrawal, anger, conduct disorders, and decreased employability. Patient perception of improvement is the best measure of successful treatment.

Benefits of Specific Recommended Treatments

Benzoyl peroxide

Benzoyl peroxide has bactericidal activity against Propionibacterium acnes (P. acnes). Benzoyl peroxide also inhibits new comedone formation, reduces follicular lipids and free fatty acids, and is available without a prescription.

Topical retinoids

Topical retinoids increase the turnover of follicular epithelial cells, promote drainage of comedones, and inhibit new comedone (blackhead, whitehead) formation.

Azelaic acid

Azelaic acid is a naturally occurring dicarboxylic acid which has been shown to be effective in reducing both inflammatory and non-inflammatory acne lesions. It has both anticomedonal and anti-bacterial action and may decrease post-inflammatory hyperpigmentation.

Topical antibiotics

The antibiotics used to treat acne have been shown to reduce colonization of P. acnes, which is thought to play a role in acne-associated inflammation. Antibiotics may also possess direct anti-inflammatory effects.

Oral contraceptives

Treatment with a combined oral contraceptive (estrogen and progestin) is an alternative for women who fail conventional acne therapies. Oral contraceptives are effective for the treatment of acne due to their androgen modulating properties.

Spironolactone

Due to its antiandrogenic effect, it has occasionally been used to treat adult onset acne in women when other treatments have been ineffective. The drug acts by blocking the effects of testosterone on the oil glands and hair follicles of the female patient. The result is a reduction in oil production that may lead to improvement of their acne.

Oral retinoids

Isotretinoin (Accutane) is highly effective in treating acne and is indicated for treatment of sever cystic recalcitrant nodular acne.

POTENTIAL HARMS

Benzoyl peroxide

- The most frequent side effect is local irritation.
- Contact allergy is possible, but rare.
- Bleaches hair and fabrics.

Topical retinoids

- The most frequent side effects are erythema, dryness, and burning, which can be minimized by applying 30 to 45 minutes after washing or by starting with lower strength formulations or alternating application in the beginning.
- Liquid and gel forms tend to be more drying than creams. New formulations (Avita® and Retin-A Micro®) are designed to be more emollient and less penetrating which may lessen irritation.
- Tazarotene (Tazorac®) tends to be more irritating; adapalene (Differin®) may be less irritating.
- This type of medication can be photosensitizing; sunscreen with a sun protection factor (SPF) of 15 to 30 is recommended.

Azelaic acid

- Local irritation, pruritis, and burning may occur.

Topical antibiotic products

- Pledgets and solution may contain isopropyl alcohol and may cause excessive drying.
- Rare case reports of pseudomembranous colitis have been reported following topical clindamycin.

Oral antibiotics

- Gastrointestinal upset is common with erythromycin (Erytabs®, generics).
- Many drugs interact with erythromycin including (but not limited to): theophylline, digoxin, anticoagulants, lipid lowering drugs, carbamazepine.
- Common adverse reactions for doxycycline, minocycline (Minocin®, generics), and tetracycline include photosensitivity, gastrointestinal upset, pseudotumor cerebri (benign intracranial hypertension).
- Adverse reactions with minocycline include abnormal pigmentation, vertigo, and rare severe drug reaction/lupus-like reaction.
- Common drug interactions with doxycycline, minocycline, and tetracycline include antacids, oral contraceptives, anticoagulants.
- Clindamycin (Cleocin®, generics) can cause severe and potentially fatal pseudomembranous colitis. Patients should be instructed to stop drug at the first sign of diarrhea and notify the physician.
- Common side effects of sulfamethoxazole/trimethoprim (Bactrim®, Septra®, generics) include allergic skin reactions and gastrointestinal disturbances.
- Common drug interactions of sulfamethoxazole/trimethoprim (Bactrim®, Septra®, generics) include (but not limited to) anticoagulants, cyclosporin, sulfonylureas.

Spironolactone

- Side effects are rare, usually related to menstrual irregularity, mild gastrointestinal upset, or headache.
- Women of childbearing age should use birth control methods while taking the medication.
- The medication should be taken for one to two years with periodic rest periods.

Oral retinoids

- Isotretinoin can cause severe birth defects if used during pregnancy.
- Other side effects include possible changes in liver function, increased cholesterol and triglycerides, dryness of the skin and mucosal surfaces including the eyes and lips (cheilitis), arthralgias, headache, photosensitization, and possible association with an onset or worsening of depression.

Intra-lesional injections

- Injections carry the risk of causing skin atrophy.
- Repeated injections are not recommended.

CONTRAINDICATIONS

CONTRAINDICATIONS

Topical Retinoids. Oral Retinoids. Spironolactone. Contraindications include pregnancy.

Sulfacetamide. Sulfamethoxazole/Trimethoprim. Contraindications include allergy to sulfonamides.

Doxycycline, Minocycline, and Tetracycline. Contraindications include children <8 years old, pregnant or nursing women.

QUALIFYING STATEMENTS

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- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they form a guideline action group.

In the action groups, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures for Health Care Systems

1. Improve the selection of appropriate treatment for patients with acne based on severity.

   Possible measures for accomplishing this aim:

   a. Percentage of patients with mild acne treated with appropriate topical medications at first visit.
   b. Percentage of patients with severe acne treated with appropriate topical and systemic medications at first visit.
2. Increase the number of patients who report satisfaction with the treatment of their acne.

   Possible measure for accomplishing this aim:

   a. Percentage of patients who report satisfaction with treatment one year after initiation of treatment
3. Increase the number of patients with appropriate follow up for acne treatment.

   Possible measure for accomplishing this aim:

   a. Percentage of patients who have documentation of follow-up in 8 to 12 weeks after initiation of treatment (excludes Accutane).

At this point in the development for this guideline, there are no specifications written for possible measures listed above. The Institute for Clinical Systems Improvement (ICSI) will seek input from the medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, measurement specifications may be included.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Acne management. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Sep. 32 p. [54 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Nov (revised 2003 Sep)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Caroline Mason, MD (Work Group Leader) (HealthPartners Medical Group) (Family Practice); Gary Oftedahl, MD (Institute for Clinical Systems Improvement) (Internal Medicine); Claire Neely, MD (HealthPartners Medical Group) (Pediatrics); Mark Davis, MD (Mayo Clinic) (Dermatology); Jennifer Lee, MD (North Clinic) (Dermatology); Maureen Guay, RPh (HealthPartners Medical Group) (Pharmacy); Jennifer Bailey, RN (HealthPartners Medical Group) (Nursing) (Health Education); Beth Green, MBA, RRT (Institute for Clinical Systems Improvement) (Measurement and Implementation Advisor); Peter Lynch, MPH (Institute for Clinical Systems Improvement) (Evidence Analyst); Barbara Mullikin, MS (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: Institute for Clinical Systems Improvement (ICSI). Acne Management. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2002 Nov. 31 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ICSI pocket guidelines. April 2004 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2004. 404 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

- Acne management. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Jan.

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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